

REMARKS

The Final Office Action of March 15, 2010, and the Advisory Action of August 30, 2010, have been received and reviewed. Claims 1, 6-11, 22, and 23 stand rejected. This application is to be amended as previously set forth. All claim cancellations and amendments are made without prejudice or disclaimer. Basis for the amendments can be found throughout the application; for example, in the previously presented claims, and in the Specification at, *e.g.*, **Examples I and II**. No new matter has been presented. Reconsideration is respectfully requested.

Telephone Interviews

Applicants appreciate the courtesy extended by the Examiner during the telephone interview of August 27, 2010. Alexander T. Stein, attorney for the applicants, sought clarification from the Examiner regarding the basis for the dismissal of the applicants' petition for acceptance of unintentionally delayed priority claims, as the Decision on Second Renewed Petition of August 23, 2010, referenced an Advisory Action that had not at that time been mailed to the applicants. Examiner Joike indicated that the Advisory Action had been prepared and would be mailed to the applicants. Examiner Joike also communicated the substance of the Advisory Action to Dr. Stein. Dr. Stein expressed concern that the Final Office Action and the Decision on Second Renewed Petition could be read together to suggest a situation where: a) the Examiner could not enter an amendment incorporating a priority claim reference to the application until a petition for acceptance of that unintentionally delayed priority claim had been granted; and b) the Office could not grant the applicants' petition for acceptance of an unintentionally delayed priority claim until a priority claim reference had been entered into the application by amendment. Examiner Joike clarified that once the applicants filed a Request for Continued Examination (RCE), the proposed amendment to the Specification could be entered and the petition decided.

Applicants further appreciate the courtesy extended by Richard M. Ross of the U.S.P.T.O. Office of PCT Legal Administration during the telephone interview of August 31, 2010. Alexander T. Stein, attorney for the applicants, sought to verify that the applicants' petition for

the acceptance of unintentionally delayed priority claims could be granted after the filing of an RCE. Mr. Ross indicated that, if all the supporting documents were in order, the applicants' petition would be granted after prosecution had been reopened by the filing of an RCE.

The applicants believe that the foregoing adequately describes both interviews. If, however, the Office believes more detail to be desirable, the Office is kindly requested to contact the applicants' attorney, and more detail will be provided to the extent available.

Priority

The present application continues to claim priority to U.S. Patent Application Serial No. 09/549,463, filed April 14, 2000, now U.S. Patent 6,855,544 B1; U.S. Provisional Patent Application Serial No. 60/129,452, filed April 15, 1999; PCT International Patent Application No. PCT/EP2003/007690, filed July 15, 2003, designating the United States of America, and published, in English, as International Publication No. WO 2004/009618A2 on January 29, 2004; U.S. Provisional Application No. 60/397,066, filed July 18, 2002; co-pending International Patent Application No. PCT/EP03/50201, filed May 27, 2003, designating the United States of America; European Patent Application No. 02077953.4, filed July 18, 2002; and U.S. Provisional Application No. 60/397,066, filed July 18, 2002.

The Office has noted that the applicants must file a petition for acceptance of unintentionally delayed priority claims in order for the present application's priority claims to be entered. Final Office Action, at pages 2-3. Applicants filed such a petition in the Office concurrently with an Amendment under 37 C.F.R. § 1.116 on May 17, 2010. As explained in the Decision on Second Renewed Petition of August 23, 2010, the applicants' petition cannot be granted by the U.S.P.T.O. Office of PCT Legal Administration until the applicants have reopened prosecution so that appropriate references to the priority documents can be added to the application. Id. Consequently, the applicants have now filed a Request for Continued Examination and the present Amendment requesting entry of the appropriate references into the application. The applicants have also filed a Renewed Petition under 37 C.F.R. § 1.78(a)(3), a copy of which is provided herewith as a courtesy to the Office.

The applicants most respectfully request that the amendments to the Specification set

forth in this Amendment be entered. The applicants respectfully submit that these amendments introduce appropriate references to priority documents into the application, and that the Office will be in a position to grant the applicants' priority claims once the applicants' renewed petition has been granted.

Objection to the Specification

The Specification stands objected to as containing priority references to PCT International Application Nos. PCT/EP03/007690 and PCT/EP03/50201, European Patent Application No. 02077953.4, and U.S. Provisional Patent Application Serial No. 60/397,066, which priority claims have not been granted. Final Office Action, at page 2. Applicants duly note the objection, and respectfully submit that the objection will become moot when the concurrently-submitted petition for amended priority rights under 37 C.F.R. §§ 1.78(a)(3), 1.78(a)(6), and 1.55(c) is granted. Applicants have submitted an amendment to the Specification with the present Amendment to comply with the Office's request. See Decision on Renewed Petition of March 9, 2010, at page 2.

Oath/Declaration

The Office asserts that the Declaration of November 20, 2006, is without effect, for the reason that a priority claim under 37 C.F.R. § 1.55 to an identified foreign application has not been made. Final Office Action, at pages 3-4. As set forth, *supra*, the concurrently-submitted petition will render this objection moot.

35 U.S.C. § 112, first paragraph

Claims 1 and 6-11 stand rejected under 35 U.S.C. § 112, first paragraph, for assertedly failing to comply with the written description requirement. Final Office Action, at page 4. Specifically, the Office asserts that, while there is support in the Specification for "various, specified times," there is "no support in the specification for a predetermined amount of time." Id. Claim 9 has been canceled, rendering the rejection of this claim moot. Without agreeing that the Specification does not provide ample description of selection for stable transfectants by

growth in selective media for predetermined times, the applicants have amended independent claims 1 (from which claims 6 and 7 depend) and 8 (from which claims 10 and 11 depend) to remove recitation of “for a predetermined amount of time.” For at least this reason, the applicants respectfully request the rejection of claims 1, 6-8, 10, and 11 under 35 U.S.C. § 112, first paragraph, be withdrawn.

35 U.S.C. § 112, second paragraph

Claims 1 and 6-11 stand rejected under 35 U.S.C. § 112, second paragraph, for assertedly being indefinite. Final Office Action, at page 4. Specifically, the Office asserts that the term, “predetermined amount of time,” is vague. *Id.* Applicants do not agree that “predetermined amount of time” renders claims 1 and 6-11 indefinite; for example, one of ordinary skill in the art would know what is meant by selecting transfectants with a selectable marker by growth in selective media for a predetermined amount of time. Applicants have canceled claim 9, rendering the rejection of this claim moot. And, the applicants have amended the remaining claims, as set forth, *supra*, to remove recitation of “for a predetermined amount of time.” For at least this reason, the applicants respectfully request the rejection of claims 1, 6-8, 10, and 11 under 35 U.S.C. § 112, second paragraph, be withdrawn.

35 U.S.C. § 103

Claims 1, 6, and 7 stand rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over U.S. Patent 6,821,512 to Gao *et al.* (hereinafter “the ‘512 Patent”) in view of International PCT Publication WO 00/63403 by Hateboer *et al.* (hereinafter “the ‘403 publication”). Final Office Action, at pages 5-7. Applicants respectfully traverse the rejection.

Applicants note that claim 9 was not subject to the rejection under 35 U.S.C. § 103(a). Without agreeing that any of claims 1, 6, and 7 are obvious in view of the cited references, the applicants have amended independent claim 1 (from which claims 6 and 7 depend) to incorporate the subject matter of claim 9. For at least this reason, the applicants respectfully request the rejection of claims 1, 6, and 7 under 35 U.S.C. § 103(a) be withdrawn.

Nonstatutory double patenting rejection

Claims 1, 6, and 7 stand rejected on the grounds of non-statutory obviousness-type double patenting as being assertedly unpatentable over claims 1, 3, 6-7, and 9 of U.S. Patent No. 7,429,486 ('486 Patent). Further, claims 1, 6, and 7 stand rejected on the grounds of nonstatutory obviousness-type double patenting as being assertedly unpatentable over claims 1, 2, and 5-7 of U.S. Patent No. 7,262,028 ('028 Patent).

Applicants note that claim 9 was not subject to a non-statutory obviousness-type double patenting rejection over either the '486 Patent or the '028 Patent. Without agreeing that any of claims 1, 6, and 7 are not patentably distinct from the claims of either patent, the applicants have amended claim 1 (from which claims 6 and 7 depend) to incorporate the subject matter of claim 9. For at least this reason, the applicants respectfully request the non-statutory obviousness-type double patenting rejections of claims 1, 6, and 7 be withdrawn.

Claims 1, 6, 7, 22, and 23 stand provisionally rejected on the ground of non-statutory obviousness-type double patenting as being assertedly unpatentable over the claims of co-pending application 12/291,881 (hereinafter "the '881 application") in view of Gao *et al.* Pursuant to MPEP § 804(I)(B)(1), the applicants respectfully submit this provisional rejection should be withdrawn, at least in view of the fact that the present application has an earlier filing date than the '881 application. The '881 application has a filing date of November 14, 2008. The present application has a filing date of August 20, 2003.

As provided for in the MPEP § 804(I)(B)(1),

If a "provisional" nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer. If the ODP rejection is the only rejection remaining in the later-filed application, while the earlier-filed application is rejectable on other grounds, a terminal disclaimer must be required in the later-filed application before the rejection can be withdrawn.

If "provisional" ODP rejections in two applications are the only rejections remaining in those applications, the examiner should withdraw the ODP rejection in the earlier filed application thereby permitting that application to issue without need of a terminal disclaimer. A terminal disclaimer must be required in the later-filed application before the ODP rejection can

be withdrawn and the application permitted to issue. If both applications are filed on the same day, the examiner should determine which application claims the base invention and which application claims the improvement (added limitations). The ODP rejection in the base application can be withdrawn without a terminal disclaimer, while the ODP rejection in the improvement application cannot be withdrawn without a terminal disclaimer.

Where there are three applications containing claims that conflict such that an ODP rejection is made in each application based upon the other two, it is not sufficient to file a terminal disclaimer in only one of the applications addressing the other two applications. Rather, an appropriate terminal disclaimer must be filed in at least two of the applications to link all three together. This is because a terminal disclaimer filed to obviate a double patenting rejection is effective only with respect to the application in which the terminal disclaimer is filed; it is not effective to link the other two applications to each other.

Id. (Emphasis added).

Accordingly, applicants respectfully request that the Office withdraw the provisional obviousness-type double patenting rejection based upon the '881 application.

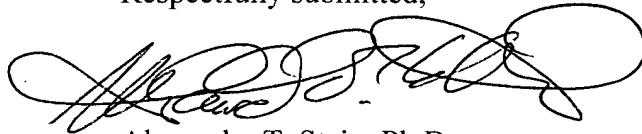
Rejoinder

Applicants respectfully request rejoinder of claims 12 and 14-20. If an applicant elects claims directed to a product, and a product claim is subsequently found allowable, withdrawn process claims which depend from, or otherwise include all elements of the allowable product claim, will be rejoined. MPEP § 821.04. Applicants respectfully submit that claims directed to a product (*e.g.*, claim 1) were previously elected by the applicants. Applicants currently believe the product claims to be in condition for allowance in view of the present amendments. As such, applicants respectfully request rejoinder of process claims 12 and 14-20, which include all the elements of an allowable product claim.

Serial No. 10/644,256

In view of the foregoing amendments and remarks, the application is believed to be in condition for allowance. If questions remain after consideration of the foregoing, the Office is kindly requested to contact the applicants' attorney at the address or telephone number given herein.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Alexander T. Stein', with a large, stylized loop at the end.

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ATS/ats

Enclosure: Petition for Acceptance of Unintentionally Delayed Priority Claims